Health Canada Santé Canada

PRODUITS THÉRAPEUTIQUES THERAPEUTIC PRODUCTS PROGRAMME

Therapeutic Products Programme

Guidelines

DISINFECTANT DRUGS

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1 INTRODUCTION

This guideline is provided to assist applicants:

- in identifying those antimicrobial products which are classified as disinfectant drugs and/or disinfectant pest control products,
- in preparing complete application packages,
- in understanding the submission options available, and
- in labelling these products to meet Canadian regulatory requirements,

This guideline supersedes the June 1994 Edition and reflects a number of changes which have occurred within the organizational structure of Health Canada and to the procedures of the Therapeutic Products Programme.

2 DEFINITION

This section describes the scientific and regulatory definitions, as well as the regulatory classification of disinfectants.

2.1 Scientific and Regulatory Definitions:

A disinfectant is an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces, and includes germicide, bactericide, fungicide, virucide, tuberculocide, sporicide, sterilant, etc.

For the purpose of obtaining a Drug Identification Number, the term "disinfectant", as used in this guideline, is considered to include gaseous or liquid sterilants, germicides, bactericides, virucides, fungicides, or combinations of these. A disinfectant without specific target organisms indicated on the product label is regarded only as a bactericide. Further information on definitions may be found in Appendix III.

2.2 Regulatory Classification

Currently, a disinfectant antimicrobial product may be classified as either or both a:

I. **drug**, as defined by the *Food and Drugs Act*:

> *any substance or mixture of substances manufactured, sold or presented for use in*
>
> *(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals*
>
> *(b) restoring, correcting or modifying organic functions in human beings or animals,*
>
> *(c) disinfection in premises where food is manufactured, prepared or kept,*

II. **control product**, as defined by the*Pest Control Products Act*:

> *any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest, and includes*
>
> > *(a) any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added, and*
> >
> > *(b) any active ingredient used for the manufacture of a control product*

Both drug and control products are regulated products in Canada and require a **Drug Identification Number** (DIN) and/or **Pest Control Product Registration Number** (PCP), respectively, prior to marketing. Products labelled as both disinfectant drugs and pest control products require both a DIN and a PCP Registration Number.

The classification of a disinfectant product as a drug and/or control product depends on the area or site of use of the product. Disinfectants are classified as **drugs**, as defined by the *Food and Drugs Act*, if the label states in specific terms, that the product is intended to be used:

> I. as a disinfectant on environmental surfaces and other inanimate objects for the mitigation or prevention of disease in humans or animals:
>
> > (a) in a facility used to manufacture, prepare, or store food under the control of a manufacturing or other commercial facility,
> >
> > or
> >
> > (b) in patient care areas of health care facilities such as hospitals, nursing homes and medical, veterinary and dental clinics.
> >
> > **or**
>
> II. for the sterilization and/or disinfection of medical devices, including, but not limited to contact lenses, hospital linens, and surgical, medical or dental instruments, such as endoscopes, catheters, aspirator tubes and thermometers.

Disinfectants and other antimicrobial products, such as sanitisers, are classified as **control products**, as defined in the *Pest Control Products Act*, if the product is for use in areas other than I and II above, such as:

> III. Products that are for disinfection or other antimicrobial purposes in the immediate environment of animals for pest control.

IV. Products that are for disinfection or other antimicrobial purposes in domestic or household applications, nonfood industrial applications, schools, swimming pools and in all circumstances other than those described as subject to the *Food and Drugs Act*.

Information Letters No. 536 and 774, issued by the Health Protection Branch (HPB) provide additional information and examples illustrating the distinction between different types of antimicrobial products (Appendices IV and V, respectively).

Note that the Therapeutic Products Programme, together with the Pest Management Regulatory Agency, is currently developing a new regulatory framework to address areas of regulatory overlap for some disinfectant products. However, until implementation of a new policy, disinfectant products continue to be regulated in accordance with the current applicable provisions of the *Food and Drugs Act and Regulations* and the *Pest Control Products Act and Regulations*.

3 APPLICATION

This section describes the division of responsibilities between the Therapeutic Products Programme and the Pest Management Regulatory Agency, the documentation required when making a DIN and/or PCP submission and the types of review options available.

3.1 Division of Responsibilities Between the Therapeutic Products Programme and the Pest Management Regulatory Agency

The Therapeutic Products Programme (TPP) is currently administering a "single window" approach, established on April 1, 1997 in cooperation with the Pest Management Regulatory Agency (PMRA), to streamline the premarket registration process and to eliminate overlapping of review activities for many types of disinfectant products.

The Therapeutic Products Programme (TPP) continues to be responsible for premarket review of applications for products classified as disinfectant drugs. In addition, the TPP is now responsible for premarket review of applications for both new and amended registrations of pest control products labelled as disinfectants, with or without associated sanitiser uses, that are used to destroy or inactivate microorganisms for the purpose of prevention of a human or animal disease. The TPP is responsible for issuance of both PCP registration numbers and/or DINs for products deemed acceptable upon completion of the premarket review. Applications (DIN and/or PCP) for the above described types of products should be sent to the Chief, Submission and Information Policy Division of the TPP (Appendix VI).

The Pest Management Regulatory Agency (PMRA) remains responsible for antimicrobial pest control products labelled with only sanitiser claims, as well as disinfectant products to be used for purposes **other than** prevention of a human or animal disease. For example, greenhouse disinfectants intended to control plant pathogens are evaluated by the PMRA. Applications for registration of material preservatives, slimicides, algaecides, swimming pool biocides, wood preservatives and oil field microbicides should also be sent to the PMRA (Appendix VI).

Applicants are referred to the PMRA guideline, Guideline for Determining Whether Disinfectant Products are Regulated by the Therapeutic Products Programme or the Pest Management Regulatory

Agency for further details regarding the division of responsibilities between the TPP and the PMRA.

3.2 Submission Documentation Required

The following lists describe the documentation required to be submitted when applying for a DIN and/or PCP Registration Number for a disinfectant product under the responsibility of the Therapeutic Products Programme. When applying for both a DIN and a PCP registration number for a single product, all of the information for the DIN application and the PCP application is required to be submitted. Only complete submission packages will be considered acceptable for review. Ensure that all the details requested on the forms are provided.

DIN SUBMISSION:

- Completed Drug Submission Application Form for: Human, Veterinary and Disinfectant Drugs - HPB/DGPS 3011 (5-99) (filename: submissn_e),
- Completed Submission Certification: DIN (filename: dincert_e) , or
  Submission Certification: Category IV Drug (filename: c4cert_e), as appropriate
- Submission Fee Application Form, DIN Submission (filename: feedin_e)
- Labelling:
  proposed Canadian labelling in conformity with the Therapeutic Products Programme guidelines.
  If the product complies with a Class Monograph, Labelling Standard or Labelling Guide, applicants should submit a letter confirming compliance with the particular standard, referenced by name and date.
- Efficacy data, as appropriate based on Evaluation Criteria (Appendix II)

PCP SUBMISSION:

- Completed PCP application form: Application for New or Amended Registration
- Completed Product Specification Form: Instructions for Control Product Specifications Form
- PCP Submission fee form: Instructions for the Applications Fee Form, and appropriate fee
- Labelling : proposed Canadian labelling in conformity with the *Pest Control Products Act and Regulations*.
  If the product complies with a Labelling Guide, applicants should submit a letter confirming compliance with the particular standard, referenced by name and date.
- Confirmation of use of a registered source of active ingredient(s)
- Efficacy data, as appropriate

Applicants may find the following documents useful in completing the DIN and/or PCP submissions:

DIN

- *Food and Drugs Act and Regulations*
  The drug submission application form should be completed using the information specified in Section C.01.014.1
- Preparation of Drug Identification Number Submissions (1995) (filename: prepdin_e)
- Labelling of Drugs for Human Use (Cat. No. H42-2-2-1989)
- Good Manufacturing Practices: GMP Guidelines 1998 Edition (filename: gmpguid98_e)

- Assessment of Efficacy of Antimicrobial Agents for Use On Environmental Surfaces and Medical Devices CGSB - 2.161-97

PCP

- Pest Control Products Act and Regulations
- Registration Handbook for Pest Control Products
- Regulatory Directive T-1-215 Efficacy Data for Antimicrobial Products

3.3 Application Options

A number of application options have been developed to provide abbreviated reviews for certain groups of disinfectant products and to respond to common types of application requests. It is important to note that all disinfectant submissions are handled according to the Therapeutic Products Programme's Policy on Management of Drug Submissions, which includes target performance standards for submission reviews.

3.3.1 Abbreviated Reviews

If a disinfectant product and its labelling comply with all the criteria in an existing Class Monograph, Labelling Standard or Labelling Guide, then the product qualifies for an expedited review, with a performance target of 45 days, and efficacy data is not required to be submitted with the application. Currently, there are the following Class Monographs, Labelling Standards and Labelling Guide for disinfectant products, which can be found in the indicated Appendices to these guidelines:

Title	Appendix
Category IV Monograph: Hard Surface Disinfectants	VII
Category IV Monograph: Contact Lens Disinfectants	VIII
Category IV Monograph: Toilet Bowl Disinfectant Cleaners	IX
Labelling Standard: Quaternary Ammonium Compounds for Use Against HIV	X
Labelling Standard: Ethylene Oxide Gaseous Sterilants	XI
Standard Labels for Quaternary Ammonium Hard Surface Disinfectant Products	XII
Labelling Guide: Sanitisers / Cleaners	XIII

3.3.2 Full Reviews

If a disinfectant product and its labelling do not meet all the criteria in an existing Class Monograph, Labelling Standard or Labelling Guide, then a full review is required, with a 210 day performance target. Appropriate efficacy data should be provided with the submission to support the labelling claims, as indicated in Appendix II.

3.3.3 Changes to Products Currently on the Canadian Market

For disinfectant drug products, a new Drug Submission Application is required if there is any change to the fabricator's name, product name, form, route of administration, premises for disinfection or quantitative list of active ingredients (e.g. new active ingredients, changes to the strength of the active

ingredients, etc.) (Section C.01.014.1 (2) (a) to (f) of the *Food and Drugs Act and Regulations*). For such changes, applicants or submission sponsors are asked to submit a Drug Submission Application, description of the changes, copies of the old and new labelling with highlighted changes, Drug Identification Number (DIN) submission certification, fee form, fee, and supporting data, as appropriate, to the Chief, Submission and Information Policy Division (Appendix VI).

For disinfectant drug products, a new Drug Submission Application is not required if the change is limited to the type of use (human, veterinary, disinfection in premises), nonmedicinal colouring ingredients, use or purpose, dosage, or address of the manufacturer (Section C.01.014.1 (2) (g) to (k) of the *Food and Drug Regulations*). In this case, the Therapeutic Products Programme must be notified of the change in writing within 30 days, by contacting the Chief, Submission and Information Policy Division (Appendix VI). The desired change will be screened to determine if a review is required. If the nature of the changes results in a significant change in the use, purpose or safety of the product, then submission of an application for a DIN is recommended.

For pest control products, a change in the subject matter regarding the product requires the registrant to notify by letter or submit an Application for New or Amended Registration, together with copies of the old and new labelling with highlighted changes, fee, fee form, Product Specification Form and supporting data, as appropriate. This information should be submitted to the Chief, Submission and Information Policy Division (Appendix VI). For complete details, consult the Pest Management Regulatory Agency's Regulatory Directive DIR 94.01 Notification / Non-Notification

3.3.4 Assignment of Drug Identification Numbers (DINs) According to Product Name

The Therapeutic Products Programme's Policy: DIN: Assignment According to Product Name, April 14, 1998, (filename: asigndin_e) defines the options available for the assignment of Drug Identification Numbers (DINs) to applicants or submission sponsors who may, or may not, wish to identify a distributor or retail outlet on the label as part of the brand name.

Many of these types of DIN submissions, previously known as "duplicate products" or "private labels", may be processed directly, with a 45 day performance target, provided that the applicant provides the following:

- a DIN application, together with a draft of the new label, reflecting the change in brand name and/or the name of the fabricator and/or distributor, as appropriate;
- a copy of the labelling most recently authorized by the Health Protection Branch.
- a letter signed by the company which:

  i) indicates the brand name, DIN and date of issuance, and fabricator of the "original" product, and;

  ii) states that all aspects of the submission, with the exception of the name of the distributor (and the brand name, if applicable) are identical to that of the "original" submission;

- for cross-referenced submissions, a letter from the company holding the DIN for the marketed product authorizing HPB to access their data to support the submission for the second product.

3.3.5 Change in Fabricator's Name and/or Product Name

The Therapeutic Products Programme's Policy: Changes in Manufacturer's name and/or Product Name, April 24, 1998, (filename: mfrname_e) defines the conditions and procedures for the administrative processing of drug submissions pertaining to a change in manufacturer's name and/or product name following a merger, buy-out or other corporate restructuring or as a result of a licensing agreement.

If a fabricator's name changes and/or the product name for a marketed drug product changes, a DIN Submission for each affected drug product must be submitted to the Chief, Submission and Information Policy Division (Appendix VI). The fabricator may request to keep the same DIN or request a new DIN. These types of DIN submissions are processed administratively, with a 45 day performance target, provided that:

- The product is currently marketed (notified) in Canada.
- a signed certification is submitted for the product, certifying that all aspects of the product and labelling material are identical to those previously authorized for that product, except for the changes to the fabricator's name and/ or the product name.

In the case of a product name change, the submission for the proposed name change must not make a claim that conflicts with the conditions of the previously issued DIN.

4 LABELLING

This section is intended to help the applicant in preparing acceptable labelling for disinfectant drugs. Applicants should also refer to Sections C.01.004 and C.01.005 of the *Food and Drugs Act and Regulations* and be prepared to provide, on request, evidence of safety and efficacy for the stated claims or uses.

Information specific to the labelling of disinfectant pest control products may be found in the Registration Handbook for Pest Control Products, November 1998.

The applicant must submit all draft labelling (e.g. for the inner and outer packages, for the activator, promotional material, etc.) for the drug product with the DIN submission.

As certain requirements are clearly defined in the *Food and Drugs Act and Regulations*, assessment of these aspects of the labelling are excluded from routine evaluation. Examples include:

- Location of the Drug Identification Number (DIN) on the main panel of the label.
- Declaration of the Net Contents. Disinfectants are usually liquids packaged under atmospheric pressure. It is standard practice to declare this item using volume units (e.g., 500 mL). Powders, solids, and aerosol sprays are usually declared in mass units (e.g., 500 g). Tablets or other forms of unitized packaging are usually declared by count. Volume and mass must be expressed in metric units, using proper abbreviations (e.g., 250 g, 500 ml, or 1 L).
- Declaration of the Lot Number. The lot number is assigned by the manufacturer to a production batch or unit. This number, composed of letters or figures or both, must appear on the product's label or container. The lot number that appears on the product must be traceable in manufacture and identifiable in distribution. It must be preceded by any one of the following: Lot; Lot Number; Lot No.; or (L).
- Inclusion of appropriate symbols and cautionary statements for pressurized metallic containers

(Section A.01.061 - A.01.063 of the *Food and Drugs Act*).

- Expiration dating of the product in its marketed packaging (Section C.01.004 of the *Food and Drugs Act and Regulations*).
- Security packaging requirements for disinfectants for contact lenses, including a statement or illustration drawing attention to the security feature (Section A.01.065 of the *Food and Drugs Act*).

Applicants should also consider the following particulars when preparing labelling for a disinfectant drug.

4.1 Name of the Product

The label must state the brand name for the disinfectant, that has been selected by the applicant or submission sponsor.

4.2 Name and Address of the Submission Sponsor

The name of the submission sponsor, who is responsible for the product and to whom the DIN is assigned, must appear on the label of the product. If the address of the submission sponsor is not in Canada, then the name and address of the principal place of business in Canada of the importer or agent must also appear on the label. In either case the address must be sufficiently detailed that a letter bearing that address can be delivered. It is common practice to give a complete mailing address.

> The *Food and Drugs Act and Regulations* (Section A.01.010) define a "manufacturer" as: a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug.

4.3 Active Ingredients

The identity and concentration of each active ingredient in the product must be stated. "Active" (or "medicinal") ingredients are those ingredients which impart the antimicrobial activity to the product. Concentration is usually expressed as a percentage on a weight-per-volume basis (e.g., 0.25 % w/v). Using this information and the dilution rate stated under the directions for use, to calculate the in-use concentrations of the active ingredients.

If the disinfectant is also subject to the *Pest Control Products Act*, the guarantee statement that identifies the active ingredient on a weight-per-volume basis will normally be considered acceptable for the declaration of active ingredients under the *Food and Drugs Act*.

4.4 Intended Use

This section describes the information that is considered to be necessary to clearly communicate the purpose of the product .

4.4.1 Claims

The label must clearly identify the purpose of the product (e.g. as a disinfectant, gaseous or liquid sterilant, germicide, bactericide, virucide, fungicide, etc. or a combination of these), so that the user

will clearly understand its intended uses and limitations.

4.4.2 Area or Site of Use

The label must indicate the type of facility where the disinfectant product is to be used (e.g., premises where food is manufactured, processed or kept, health care facilities, etc.) and the types of inanimate objects (e.g., work surfaces, floors, walls in patient care areas, etc.) or medical devices (e.g., bronchoscopes, bedpans, contact lenses, etc.) to be disinfected. In addition, for contact lenses the type of lens (e.g., soft, hard, gas permeable, etc.) must be specified.

The various uses may be separated on the label. For example, the word "disinfectant" may be part of the product name and "for use on floors and walls in health care facilities such as hospitals, nursing homes, etc." may appear elsewhere on the label, even as part of the directions for use.

If there are several intended drug uses, although a separate statement for each use is preferred, similar uses can be grouped together. In any case, there must be no ambiguity to the user regarding the intended use of the product, or how it is to be employed for each of its intended uses.

With respect to the disinfection of medical devices, the device and the manner in which it is used must be considered. The "Spaulding Classification" (Appendix I) is generally accepted as a strategy for the classification of medical devices that contact the patient and the establishment of levels of germicidal activity required for disinfection/sterilization. This classification is important in determining the characteristics of the disinfectant and the type of efficacy data that is required (Appendix II).

4.5 Directions for Use

Directions for use must provide explicit information relevant to the effective use of the disinfectant. The following are examples of factors which should be considered:

I. The label must provide specific instructions to the user for preparing the in-use dilution of the product to achieve the intended antimicrobial effect. Metric units or ratios must be used. For example: "Dilute 25 mL of product to 1 L with water," or "Mix 1 part product with 39 parts water". Quantities may also be expressed in non-metric units, but they must be clearly identified to avoid confusion (e.g., 3.79 L (1 U.S. gallon)).

   More than one dilution may be specified if several different applications are intended . The dilution that is intended for each application must be clear to the user. Acceptable different applications are considered to be uses that are easily discernible by the user (e.g. floors and walls, toilet bowl disinfection, semi-critical medical devices, etc.). It is not considered to be acceptable to indicate different dilution levels for use against specific microorganisms or groups of microorganisms, since a user is unable to readily determine which microorganisms are present on a target surface. Additional information about dilutions for non-drug applications, such as sanitizing and precleaning, is permitted on the label, provided that these uses are separate and clearly identified.

II. Products marketed as aerosol sprays or as wipes or towelettes are generally assessed on the basis of the efficacy of the liquid disinfectant itself. The directions for use must clearly indicate that the surface is to be thoroughly wetted and left as such for the appropriate contact time, i.e., the spray or towelette is regarded simply as a means of applying the disinfectant to the surface. If the product is intended to be used for other purposes, e.g., a "spray and wipe", the manufacturer should submit data to support claims of efficacy for use under these conditions.

III. Contact times (i.e., the length of time the disinfectant must be in contact with the surface to achieve disinfection) must be stated. More than one contact time may be specified if several different applications are intended . The contact time that is intended for each application must be clear to the user. Acceptable different applications are considered to be uses that are easily discernible by the user (e.g. floors and walls, toilet bowl disinfection, semi-critical medical devices, etc.). It is not considered to be acceptable to indicate different contact times for use against specific microorganisms or groups of microorganisms, since a user is unable to readily determined which microorganisms are present on a target surface. For example, it is not considered acceptable to make reference to a 5 minute contact time for efficacy against vegetative bacteria and a 10 minute contact time for efficacy against fungi.

IV. If the product is to be used at a temperature other than 20^{o} C, this temperature must be specified and the label must indicate that heating to the specific temperature is required for efficacy.

V. If applicable, the volume and directions for the use of an activator must be included.

VI. The efficacy of a disinfectant may diminish with time or the conditions under which it is used. Therefore, in addition to the expiry date of the product in its original packaging, the labelling for products not labelled for single use must clearly indicate the expiry dating of the product after activation or dilution and under re-use conditions, as appropriate. It is recognized that an "official" procedure for establishing the expiry date for re-use solutions has not yet been defined. Nevertheless, in order to claim that a product is for re-use, data demonstrating efficacy of the product under labelled re-use conditions is required for each labelled application. The use of chemical test strip indicators or ampoules should be specified with clear directions for use. Applicants are encouraged to emphasize on the product labelling that monitoring of the concentration(s) of active ingredient(s) of the product before each use may be necessary and that the user is not to rely entirely on the elapsed time (days in use). It would also be useful for applicants to consider stating acceptable types of containers for re-use of the disinfectant, as well as the specifications for re-use, such as contact time, temperature, and minimum effective concentration of active ingredients.

VII. The presence of organic soil reduces the effectiveness of disinfectants. Therefore, labelling for disinfectants for use on medical devices must specify that the device is to be thoroughly cleaned prior to its disinfection. It is also appropriate to indicate that heavy soil is to be removed from environmental surfaces prior to disinfection.

VIII. Appropriate rinse procedures to ensure the absence of potentially harmful residues on the surface or device after disinfection or sterilization are required. For example, for premises where food is manufactured, processed or kept, a statement to the effect that, if used on surfaces which come into contact with food, the surfaces must be thoroughly rinsed with potable water after disinfection, is required unless otherwise stated indicated by the Bureau of Chemical Safety, Food Program, Health Protection Branch (Appendix VI, Appendix XIII). For devices, specific instructions for rinsing the devices to remove all trace of the disinfectant and disinfectant by-products are required (e.g., rinse thoroughly with sterile water, potable water, saline, etc. as appropriate). Rinse procedures for critical and semi-critical instruments must ensure that the level of hygiene achieved is not compromised (sterility or high-level disinfection,

respectively).

IX. It is not acceptable to make reference to "Repeat if necessary" or similar wording in the directions for use. Complete directions for use should include all aspects such as pre-cleaning requirements, dilution rate, contact time, contact temperature, etc., that result in efficacy of the product for all labelled claims.

X. For products labelled with claims against HIV, the following additional labelling criteria must be included:

a) There should be no reference to the treatment or prevention of "AIDS", a Schedule A disease, on the labelling. The term "HIV" is acceptable, but should also be identified as "Human Immunodeficiency Virus".

b) Directions for use should indicate that the product is intended for use against HIV only in those settings where the virus would be expected to be encountered, such as settings where contamination by blood or body fluids is likely.

c) Directions for use should also provide specific decontamination procedures, including:

i) The need for surfaces to be cleaned prior to disinfection should be identified.

ii) Personnel that clean items soiled with blood or body fluids should be cautioned to wear appropriate barrier protection, such as disposable gloves, gowns, and masks.

iii) Directions for the disposal of cleaning materials and waste should be specified.

iv) Directions for proper dilution and application of the disinfectant, including appropriate contact times, should be given.

XI. At the present time, it is HPB policy not to permit claims of efficacy against Hepatitis viruses (B and C), unless the applicant can provide data to demonstrate efficacy against Hepatitis viruses using a methodology which has been accepted by an internationally recognized standards organization and is based on the infectivity of the virus.

4.6 Safety and Efficacy Testing

Submission sponsors responsible for the product must have data available to provide to Health Protection Branch (HPB) on request, to establish the safety of their product for its intended use. In addition to acute and chronic toxicity and other safety issues related to the use of the product, the presence and significance of potential residues is important, especially with respect to food and medical devices which contact persons directly.

Submission sponsors must also have evidence available to support all claims stated on the label and must provide this evidence, on request, for evaluation by Health Protection Branch (HPB). The minimum evaluation criteria for disinfectants (excluding gaseous sterilants and contact lens disinfectants) generally recommended by Health Protection Branch (HPB), are outlined in Appendix II. Appendix II also identifies those situations which require the inclusion of efficacy data with the DIN submission (e.g. for disinfection of medical devices, claims for efficacy against mycobacteria,

HBV, HIV, etc.). Disinfectant products which meet all of the criteria of an existing class monograph or labelling standard, do not require the submission of efficacy data with the DIN application.

When designing test protocols, it is recommended that as a minimum, manufacturers consider the Canadian General Standards Board (CGSB) guideline, Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices (CAN/CGSB-2.161-97) (CGSB website). Applicants should note the following requirements:

- the data used to establish the safety and efficacy of a product must relate directly to its formulation, as the safety and efficacy of a particular ingredient may be affected by other components of the formulation.
- evidence of efficacy of the product must be available to support claims of efficacy against specific microorganisms.
- efficacy data should be generated using product which is aged/stressed to the limit of its stated re-use period, for products having an expiry date and re-use life expectancy.
- testing of at least 3 samples, representing at least 3 separately compounded batches of product is included in the recommended CGSB methodology.
- labelled temperature for disinfection should be supported by efficacy testing conducted at the same temperature. For disinfection of inanimate environmental surfaces the test temperature should not exceed 20°C, as indicated in the recommended CGSB methodology.
- For products involving efficacy against mycobacterium, it is also recommended that an additional quantitative test be considered as part of the protocol.

For efficacy testing of disinfectants that are for use with a chemiclave, applicants should conduct testing under conditions that are consistent with use of the product as labelled, (i.e., inoculated carriers should be exposed to the recommended chemiclave cycle). Providing test data generated using the disinfectant alone is generally considered insufficient. In addition, the product labelling should clearly specify the type of chemiclave (make, model, etc.) and the cycle (pressure, temperature, time, etc.) with which the disinfectant is intended to be used. Applicants may find the following guidelines to be sources of useful information:

- Guidance on the Content and Format of Premarket Notification {510(k)} Submissions for Liquid Chemical Germicides, 1996. United States Food and Drug Administration.
- Premarket Notification {510K} Guidance Document for Contact Lens Care Products, (filename: contlens.pdf) 1997. United States Food and Drug Administration.

4.7 Precautionary Statements

Appropriate precautionary statements and symbols for the safe and effective use of the product are required. The outer label should carry the precautionary symbols, signal words and hazard statements. Other precautionary statements and information may be placed on an inner label, provided that there is reference to them on the outer label. Examples of such precautionary statements which may be appropriate include:

- keep out of reach of children
- not for internal use
- use in ventilated area
- avoid contact with eyes; use safety glasses; in case of contact, flush with water immediately and contact a doctor

- avoid contact with skin; use gloves; in case of contact with skin, flush immediately and thoroughly with water
- avoid contact with food
- may damage or corrode designated surfaces or device components
- not intended for use directly in the eye (disinfectants for contact lenses)

Phenolic disinfectants require a statement to the effect that the product is not to be used in hospital nurseries.

For further guidance on appropriate precautionary labelling, applicants are referred to:

- the Consumer Chemicals & Containers Regulations (CCCR) of the *Hazardous Products Act* (Appendix VI)
- Schedule III of the *Pest Control Products Act and Regulations*
- Part 7 of the Registration Handbook for Pest Control Products

4.8 Colouring Agents

Any colouring agent may now be used in disinfectant products, unless there is a safety issue related to its use, in accordance with Section C.01.040.2 (5) of the *Food and Drugs Act and Regulations*.

5 REFERENCES

1. ***Self-Medication. A Reference for Health Professionals***,4th Edition, 1993. Canadian Pharmaceutical Association, Ottawa.
2. ***American Handbook of Nonprescription Drugs***, 11th Edition, 1996. American Pharmaceutical Association, Washington.
3. ***Martindale, The Extra Pharmacopoeia***, 31st Edition, 1996. Royal Pharmaceutical Society, London.
4. ***Remington: The Science and Practice of Pharmacy***, 19th Edition, 1995. Philadelphia College of Pharmacy and Science, Pennsylvania.
5. ***Drug Facts and Comparisons***, 1989. J.B. Lippincott Company, Facts and Comparisons Division, St. Louis, Missouri.
6. Rutala, W. A. (1990). ***APIC Guideline for Selection and Use of Disinfectants***. American Journal of Infection Control. 18:99-117.
7. Favero, M.S. and W.W. Bond. (1991). Chemical Disinfection of Medical and Surgical Materials. In ***Disinfection, Sterilization and Preservation***, 4th Edition, S.S. Block (Ed), Lea and Febiger, Philadelphia, pp. 617-641.
8. Block, S.S. (1991) Peroxygen Compounds. In ***Disinfection, Sterilization and Preservation***, 4th Edition, S.S. Block (Ed), Lea and Fibiger, Philadelphia, pp. 167-181.
9. O'Connor, D.O. and J.R. Rubino. (1991) . Phenolic Compounds. In ***Disinfection, Sterilization and Preservation***, 4th Edition, S.S. Block (Ed), Lea and Fibiger, Philadelphia, pp. 204-224.
10. ***Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices*** (CAN/CGSB: 2-161-97), Canadian General Standards Board (Appendix VI).
11. Garner J.S. and M.S. Favero. ***Guidelines for Handwashing and Hospital Control***, Hospital Infections Program, CDC, Atlanta, Georgia, 1985.
12. Favero M.S. and W.W. Bond. (1995). Antisepsis, Disinfection, and Sterilization in Hospitals

and Related Institutions. In ***Manual of Clinical Microbiology***, American Society for Microbiology, pp. 227-245.

13. Guidance on the Content and Format of Pre-market Notification 510(k) Submissions for Liquid Chemical Germicides,(1996). Food and Drugs Administration of the United States, Infection Control Devices Branch, Division Dental, Infection Control and General Hospital Devices, Office of Evaluation.
14. Infection Control Guidelines: Handwashing, Cleaning, Disinfection and Sterilization in Health Care, Health Canada, December 1998.
15. Disinfection Practices for Endoscopes and other Semi-critical Items. **Infection Control and Hospital Epidemiology**, 1991, 12(5):282-288.
16. Drugs Directorate Guidelines: Preparation of Drug Identification Number Submissions, Health Protection Branch, Health Canada, February 1995.

APPENDIX I: Classifications

Device	Definition	Disinfectant	Definition
Critical	Present a high risk of infection if they are not sterile, i.e.,contaminated with any organism, including spores. Routinely penetrate the skin or mucus membranes into normally sterile areas of the body, (e.g., implants, scalpels, needles, surgical instruments, laparoscopes), or come into direct contact with recirculating body fluids, (e.g., kidney dialysis tubing and dialyzers, or blood oxygenators).	Sterilant	A germicide which achieves sterilization.
Semi-critical	Contact with mucous membranes during use but do not usually penetrate normally sterile areas of the body, e.g., endoscopes, anesthesia breathing circuits, respiratory therapy equipment, dental mirrors, etc.	High-level Disinfectant	A germicide that kills all microbial pathogens, except bacterial endospores, when used according to labelling.
Non-critical	Contact only intact skin during routine use, e.g., stethoscopes, bedpans, etc.	Intermediate-level Disinfectant	A germicide that kills all microbial pathogens, except bacterial endospores, when used according to labelling.
		Low-level Disinfectant	A germicide that kills most vegetative bacteria and lipid or medium-sized virus, when used according to labelling.

APPENDIX II: Evaluation Criteria

Claim[1]	Device or Surface[2]	Efficacy[3]
Chemical Sterilant or Sporicide	Any device or surface	CGSB (AOAC) Sporicidal Test [4,5,6]
Tuberculocide	Semi-critical devices Non-critical devices or environmental surfaces in health care facilities.	CGSB (AOAC) Tuberculocidal Test [4,5,6]CGSB (AOAC) Tuberculocidal Test [4,5,6]
Virucide	Semi-critical devices	CGSB Testing of Virucides (Polio I virus) [4,5].
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	CGSB Testing of Virucides. If efficacy against Polio I has not been demonstrated, efficacy against specific viruses must be demonstrated and these viruses named on the label.Efficacy data and specific directions for use required if HIV is involved [4].

Fungicide	Semi-critical devices	CGSB (AOAC) Fungicidal Test [4]
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	CGSB (AOAC) Fungicidal Test
Disinfectant	Semi-critical devices (High-level Disinfectant)	CGSB (AOAC) Sporicidal test. Chemosterilant in not more than 10 hours [4,6]. CGSB (AOAC) Tuberculocidal test. Disinfectant contact time not less than that required for tuberculocidal activity [4,6].
	Intermediate-Level Disinfectant	CGSB (AOAC) Tuberculocidal Test. Disinfectant contact time not less than that required for tuberculocidal activity [4,7].
	Non-critical devices and environmental surfaces in health care facilities (Low-level Disinfectant)	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella, Staphylococcus and Pseudomonas.
	Environmental surfaces in premises where food is manufactured, processed or kept.	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella and Staphylococcus, as a minimum.

(1) Except for the purpose of the precleaning or storage of devices before or after sterilization, only sporicidal claims are acceptable for critical devices.

(2) The type of device (e.g., Spaulding classification (7,14), Appendix I), environmental surface or area must be specified on the label, with examples, as appropriate.

(3) These criteria are not directly applicable to gaseous sterilants or disinfectants for contact lenses.

(4) Supporting data is to be submitted with the DIN application.

(5) Virucidal data to support a claim for efficacy against HIV are required to be submitted with the DIN application only if conditions of use for efficacy against HIV (e.g. contact time, temperature, dilution rate etc.) differ from conditions of use for other claims.

(6) The titre of the inoculum must be sufficient to be able to demonstrate at least a 6 log kill.

(7) The titre of the inoculum must be sufficient to be able to demonstrate at least a 4 log kill.

APPENDIX III: Definitions

The definition of Sanitizer was taken from the Registration Handbook for Pest Control Products.

> ***Sanitizer*** - A product that reduces the level of microorganisms present by significant numbers, (e.g. $3\log_{10}$ reduction or more), or to acceptable levels established by federal or provincial health authorities.

The following definitions are based on those from the publication ***Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices***, CAN/CGSB-2.161-97.

> ***Disinfectant*** - An antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces. A disinfectant without specified target organisms on the container label is regarded only as a bactericide.
>
> ***High-level Disinfectant*** - A disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores when used in accordance with labelling.
>
> ***Hard Surface Disinfectant (Low-level disinfectant)*** - A disinfectant that kills most vegetative

bacteria and lipid or medium-sized viruses.

Chemosterilant - An antimicrobial agent capable of destroying all forms of micro-organisms (including bacterial spores) on inanimate surfaces.

Sporicide - An antimicrobial agent capable of destroying bacterial spores.

Virucide - An antimicrobial agent capable of destroying viruses.

Bactericide - An antimicrobial agent capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.

Germicide - Synonymous with disinfectant.

Fungicide - An antimicrobial agent capable of destroying fungi, including their spores.

Mycobactericide - An antimicrobial agent capable of destroying mycobacteria.

Tuberculocide - Synonymous with Mycobactericide.

APPENDIX IV: Information Letter 536

The content of Information Letter 536 is provided , verbatim, for convenience. However, please note that the contact information and some procedural information are no longer valid. Applicants should consult Appendix VI for updated contact information.

Date: September 15, 1978 I.L. No. 536

TO: All Manufacturers and Distributors of Disinfectants

SUBJECT: **Antimicrobial Products Subject to the Pest Control Products Act and Food and Drugs Act**

The former agreement (as reflected in Trade Information Letter 312) on the application of statutory responsibilities under the Pest Control Products Act and the Food and Drugs Act has been revised and updated by the Food Production and Marketing Branch, Plant Products Division, Agriculture Canada and by the Health Protection Branch, Health and Welfare Canada.

This revision clarifies some areas of jurisdiction and incorporates certain changes considered necessary as a result of the experience gained from the application of new authorities embodied in the Pest Control Products Act as revised in 1969 and new Pest Control Products Regulations adopted in 1972.

This Information Letter together with Information Letter 478 of September 3, 1976 regarding Medicated Feeds and Veterinary Drugs replaces Trade Information Letter 312.

By interdepartmental agreement the following administrative guidelines apply in the regulation of the products described in respect to purpose, in order to avoid duplication and to reflect the responsibilities of each agency in the application of regulatory requirements.

Products to be Regulated Under the Pest Control Products Act

1. Products for the control of non-parasitic arthropods on or in humans or for the control of arthropods on or in domestic animals, where such products are administered by topical application.
2. Products that are used in the immediate environment of animals for pest control. (Refer to exemption 3(a)(iv) of the Pest Control Products Regulations)
3. Products, other than antimicrobials, that are for insect and other pest control in premises in which food is manufactured, prepared or kept. (Refer to 3(a)(iv) of the Pest Control Products Regulations)
4. Products that are for disinfection or other antimicrobial purposes in domestic or household applications, nonfood industrial applications, schools, swimming pools and in all circumstances other than those described as subject to the Food and Drugs Act and exempted by sections 3(a)(i), (iii), (iv) and (v) of the Pest Control Products Regulations.

Inquiries relating to items identified in the foregoing sections are to be directed to:

The Chief,
Control Products Section,
Plant Products Division,
Agriculture Canada,
Sir John Carling Building,
OTTAWA, Ontario
K1A 0C5

Products to be Regulated Under the Food and Drugs Act

Antimicrobial products bearing use claims or application instructions associated with drug uses; medical care and the prevention or treatment of disease and the preservation and protection of food during its manufacture, preparation, cooking or processing, all of which are subject to the Food and Drugs Act and are exempted by section 3(a)(i), (iii), (iv) and (v) of the Pest Control Products Regulations.

The following use claims illustrate such applications or use situations:

A. **On or in Humans or Domestic Animals (section 3(a)(i),Pest Control Products Regulations)**

Antimicrobial soaps, creams, sprays, liquids, for direct application to humans or domestic* animals.

Hospital/Medical Associated Uses (section 3(a)(iii), Pest Control Products Regulations)

Antimicrobial claims for:

B. 1. Surgical, medical and dental instruments, including but not limited to,

(a) scalpels, cardiac catheters and plastic components of the heart/lung oxygenator;
(b) aspirator tubes, thermometers and telescopic instruments;
(c) face masks, operating tables and other accessory medical equipment;
(d) gauze, bandages and similar dressings;
(e) hospital linens, bedsheets, etc.

A. 2. Furniture, floors, walls and lavatory articles in hospitals.

Food Manufacturing and Processing Plants (section 3(a)(iv),Pest Control Products Regulations)including

but not limited to:

A. 1. Bakeries
2. Liquid beverage bottling plants
3. Dairy industry premises (milk rooms on farms)
4. Canneries
* includes household pets as well as livestock
5. Slaughterhouses
6. Meat-packing plants
7. Fish processing and packaging plants.

Areas in which Food is Prepared or Kept (section 3(a)(iv) , Pest Control Products Regulations)including but not limited to:

A. 1. Food storehouses
2. Butcher shops
3. Food contact areas of restaurants, hotels or other commercial operations, including food contact areas of hospitals and clinics.

Food Preservatives (section 3(a)(v),Pest Control Products Regulations)

C. 1. Treatments for preserving foods.
B. 2. Chemicals or devices for water purification.

Inquiries relating to items identified by the letter **"A"** are to be directed to:

The Director,
Bureau of Drug Surveillance,
Drugs Directorate,
Place Vanier, Tower B,
VANIER, Ontario
K1A 1B8

Inquiries relating to items identified by the letter **"B"** are to be directed to:

The Director General,
Environmental Health Centre,
Tunney's Pasture,
OTTAWA, Ontario.
K1A 0L2

Inquiries relating to items identified by the letter **"C"** are to be directed to:

The Director,
Bureau of Chemical Safety,
Food Directorate,
Tunney's Pasture,
OTTAWA, Ontario.
K1A 0L2

Review Procedures Regarding Multiple Claims

A considerable number of antimicrobial products bear label claims and use directions that render them subject to both

the Food and Drugs Act and the Pest Control Products Act. An example would be a disinfectant product represented for use in both hospitals and schools. As noted in this guideline the directions for use in hospitals make the product subject to the Food and Drugs Act while those for schools, to the Pest Control Products Act.

Applications for the registration of antimicrobial products bearing claims subject to both the Pest Control Products Act and the Food and Drugs Ac and received in the Control Products Section will be treated as follows: The applicant will be informed that the designated claims make the product subject to the Food and Drugs Act and that he should satisfy himself that the product complies with that Act by contacting the appropriate authority.

Notwithstanding the previous paragraph, use situations involving areas in which food is manufactured, prepared or kept, represent a special case. Products carrying mixed claims for this particular situation will be forwarded to the Bureau of Drug Surveillance for the review. Registration will **not** be granted without the concurrence of the Health Protection Branch.

In addition to clarifications relating to use areas, as recorded above, the following interpretations have been elaborated:

(1) A claim for the **mitigation** or **prevention** of **disease** in man or animal renders a product subject to the Food and Drugs Act.

(2) A claim for the **control** of an organism on an inanimate object renders a product subject to the Pest Control Products Act **unless** exempted by section 3(a)(iii), (iv), or (v) of the Pest Control Products Regulations.

(3) Where a product is a "dual purpose insect repellent" e.g., sunscreen/insect repellant - it is to be treated according to the procedure set down for mixed claims involving "nonfood" uses.

A. B. Morrison, Ph.D.

Assistant Deputy Minister

APPENDIX V: Information Letter 774

The content of Information Letter 774 is provided, verbatim, for convenience. However, please note that the contact information and some procedural information are no longer valid. Applicants should consult AppendixVI for updated contact information.

Date: February 20, 1990 I.L. No. 774

TO:

Disinfectant Manufacturers and Distributors

Hospitals
Health Professional Licensing Body

SUBJECT: **DISINFECTANTS FOR MEDICAL DEVICES**

For a number of years antimicrobial products labelled for use in the disinfection of medical devices have been considered as accessories to medical devices (Information Letter No. 536, 1978). Products of this type have been subject to the requirements of the Medical Device Regulations.

Concerns regarding the safety and efficacy of disinfectants have come to the attention of the Health Protection Branch in recent years. The ineffective disinfection of reusable medical devices poses a very real health hazard. Of particular concern are potential problems stemming from:

- inadequate tests or methodology used in analysis establishing efficacy,
- disinfectants labelled with claims for a use which cannot be supported given the active ingredient of the product
- inadequate quality control and finished product testing.

As a result of these concerns a review of the regulation of disinfectants, including their classification under the Food and Drugs Act has been undertaken. These products will be classified as Drugs as defined in Section 2 of the Act. As such, these products are subject to the requirements of the Food and Drugs Act and Regulations, including the requirement to obtain a Drug Identification Number (DIN) prior to sale of the product and to notify the Health Protection Branch when sale of the product has commenced, in accordance with Sections C.01.005 and C.01.014 of the said Regulations. Furthermore, this Information Letter will supersede Alert Medical Devices No. 75 issued of April 30, 1985.

To assist manufacturers in obtaining the necessary Drug identification Numbers (DIN) and in revising the labelling for their products, a deferred compliance policy will be observed. Manufacturers of disinfectants will be expected to have all stock in compliance with the notification and labelling requirements for drugs by January 1, 1991. Manufacturers are urged to submit applications for Drug Identification Numbers (DIN) as quickly as possible to provide time for the necessary evaluation of the applications.

It should be noted that these revisions do not affect the current status of products labelled for use in the disinfection of inanimate objects, other than medical devices, in premises where food is manufactured, prepared or stored or in patient care areas of hospitals. These products continue to require a Drug Identification Number (DIN) on the label prior to sale.

Information respecting these regulatory requirements may be obtained from the Chief, Pharmaceutical Assessment and Cosmetics Division, Bureau of Nonprescription Drugs, Health Protection Branch, 333 River Road, Vanier, Ontario, K1A 1B8 ((613) 954-1254).

Application forms for Drug Identification Numbers (DIN) may be obtained from and completed forms should be returned to the Drug Notification Division, Bureau of Pharmaceutical Surveillance, Health Protection Branch, 355 River Road, Vanier, Ontario, K1A 1B8 ((613) 954-6504).

A. J. Liston, Ph.D.
Assistant Deputy Minister

APPENDIX VI: Contact Information

For information concerning:

I a Drug Identification Number Information Kit for disinfectant drugs or an Information Kit for Pest Control Product Number applications, send a request including complete mailing address, telephone number, e-mail address, software application and preference for receiving the kit by e-mail, on diskette or in hard copy format (paper) to:

Information Dissemination Unit
Submission and Information Policy Division
Bureau of Policy and Coordination
Therapeutic Products Programme
Health Canada
Fax: 613-941-7284

II the regulation of disinfectant drugs, inquiries should be directed to:

Submission Management Division
Bureau of Pharmaceutical Assessment
Therapeutic Products Programme
Health Canada
A.L. #0202A1
Finance Building
Tunney's Pasture
Ottawa, Ontario
K1A 1B9
Fax: 613-941-1668

III the submission of an application for a Drug Identification Number and/or a Pest Control Product Registration number should be sent to:

Submission and Information Policy Division
Bureau of Policy and Coordination
Therapeutic Products Programme
Health Canada
A.L. #0201A1
Finance Building
Tunney's Pasture
Ottawa, Ontario
K1A 1B9
Tel: 613-941-0827
Fax: 613-941-0825

IV the acceptability of non-drug sanitizers and cleaners for use in food processing plants, inquiries should be directed to:

Chemical Health Hazard Assessment Division
Bureau of Chemical Safety
Foods Directorate
Health Protection Branch
A.L. #2201B1
Frederick G. Banting Building
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
Tel: 613-957-1709
Fax: 613-990-1543
WEB: www.hc-sc.gc.ca/food-aliment

V application requirements for 'sanitizer only' submissions subject to the *Pest Control Products Act*, inquiries should be directed to:

Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
Ottawa, Ontario
K1A 0K9
Tel: 1-800-267-6315
Fax: 613-736-3799
WEB: www.hc-sc.gc.ca/pmra-arla/

VI the acceptability of disinfectant products for use in registered food establishments, send a request for Non-Food Chemical Form (HER4031) by fax to:

Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9
Attention: J.J. Donald
Tel: 613-225-2342
Fax: 613-228-6633
WEB: www.cfia-acia.agr.ca

VII products labelled for use as antiseptics (also classified and regulated as drugs) for use on:

a) humans: inquiries should be directed to:
Bureau of Pharmaceutical Assessment
Tel: 613-954-6740
Fax: 613-954-6511

b) animals: inquiries should be directed to:
Bureau of Veterinary Drugs
Tel: 613-957-3860
Fax: 613-957-3861

VIII chemicals and materials which come into contact with drinking water, inquiries should be directed to:

Drinking Water Section Product Safety Bureau
Environmental Health Directorate
Tel: 613-952-2594
Fax: 613-952-2574
WEB: www.hc-sc.gc.ca/ehp/ehd/bch/water_quality.htm

IX The Association of Official Analytical Chemists (AOAC) Official Methods of Analysis, inquiries should be directed to:
AOAC International
Customer Service
481 N. Frederick Avenue
Suite 500
Gaithersburg, MD
20877-2417 USA
Tel: 301-924-7077
Fax: 310-924-7087
WEB: www.aoac.org

X the Consumer Chemicals & Containers Regulations (CCCR) of the Hazardous Products Act, a copy can be obtained from:

WEB: www.canada.justice.gc.ca/FTP/EN/Regs/Chap/H/H-3/index.html

XI *CGSB Sales Centre*
Place du Portage
Phase III, 6B1
Hull, Quebec
K1A 0S5
Tel: 1-800-665-2472 (Canada only)
819-956-0425 (outside Canada)
Fax: 819-956-5644
WEB: www.pwgsc.gc.ca/cgsb

APPENDIX VII: CATEGORY IV MONOGRAPH HARD SURFACE DISINFECTANTS

I) **Description:**

This monograph applies to antimicrobial products which are classified as disinfectant drugs and specifically to products which are intended to be used as environmental hard surface disinfectants in health care facilities and food processing plants. The medicinal ingredients and their concentrations in Category IV products are restricted to those specified in this monograph. The medicinal ingredients must be identified on product labelling by the names given in Appendix A of this monograph (both preferred names and synonyms are considered acceptable).

This monograph does not apply to:

a) disinfectant products to be used on medical devices or instruments, including contact lenses (ref. to Category IV product monograph forcontact lens disinfectants);

b) to products with claims for efficacy against;

- spores, as a sterilant, or as a sporicide
- the Tubercle bacilli (Tb), or *Mycobacterium*
- the Human Immunodeficiency Virus (HIV)

- the Hepatitis B Virus (HBV)

II) **Pharmaceutical Quality:**

a) All ingredients (medicinal and nonmedicinal) and finished product, should as a minimum meet the specifications of Schedule B or equivalent standard. In the absence of a Schedule B standard, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

III) **Ingredients:**

a) **Single medicinal ingredient categories:**

i) Quaternary ammonium compounds
ii) Phenolics
iii) Iodophors
iv) Chlorine releasing compounds

A list of acceptable single medicinal ingredients for Category IV hard surface disinfectants is provided in Appendix A.

b) **Combinations of Medicinal Ingredients:**

i) Combinations of any of the medicinal ingredients from the same category are permitted provided that the **total in-use concentration** of the combined ingredients is at the minimum stated in section IV) d) iv).

ii) Combinations of any of the medicinal ingredients from different categories listed in Appendix A are permitted provided that the ingredient(s) from one of the categories is present at the minimal in-use concentration as stated in section IV) d) iv), and that the ingredients do not interact in a manner that reduces the disinfectant activity.

c) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the efficacy or safety of the medicinal ingredient(s) and they must not interfere with assays and tests for the medicinal ingredients.

IV) **Labelling:**

a) This monograph describes those requirements that are specific to hard surface disinfectant drug products. Other requirements described in the *Regulations to the Food and Drugs Act* and in the **Therapeutic Products Programme guidelines: *Disinfectant Drugs*, April 20, 1999** must also be met.

b) **Unacceptable claims:**

Statements such as non-toxic, safe, non-caustic, harmless, etc. are not considered appropriate for disinfectant drugs.

c) **Indications**:

All products must indicate:

i) for use in a health care facility (e.g, hospitals, dental clinic, nursing homes) and/or a food processing plant; and

ii) one or more of the following as applicable to the product:

1. disinfectant / disinfectant cleaner
2. kills bacteria (bactericide)
3. kills viruses (virucide)
4. kills fungi (fungicide)
5. kills germs (germicide)

d) **Directions for Use**

i) For all products complete directions for use as a disinfectant for environmental surfaces including:

- types of surfaces (e.g, floors, walls, countertops);
- specific instructions for the preparation of the in-use dilution in metric units of measure;
- mode of application.
- a contact time of 10 minutes if the product is to be rinsed or wiped off;

ii) The following additional statement should be indicated if the product is to be used in a food processing establishment:

- all surfaces that come into contact with food are to be rinsed with potable water after disinfection.
- for disinfectants containing only chlorine-releasing medicinal ingredients, a rinse is not required if used at a concentration $\leq$ 200 ppm.

iii) The following additional statement should be indicated if the product contains phenolic compound(s) and is for use in health care facilities:

- not to be used in hospital nurseries.

iv) **In-use solution concentrations**

1) Quaternary ammonium compounds $\geq$ 450 ppm

2) Phenolics ≥ 700 ppm
3) Iodophors ≥ 30 ppm
4) Chlorine ≥ 100 ppm

v) **Warnings and First Aid Information**

1) For all products, should correspond to those described in the *Consumer Chemicals and Containers Regulations* to the *Hazardous Products Act* or the *Pest Control Products Regulations* as indicated in the following table:

CATEGORY	CRITERIA	REFERENCE	ALTERNATIVE
Chlorine-releasing compounds	available Cl < 1%	Section 22 CCCR[1]	Schedule III of the PCP[2] Regulations [Section 27(c)]
Chlorine-releasing compounds	1% ≤ available Cl < 4%	Section 22 CCCR[1]	
Chlorine-releasing compounds	4% ≤ available Cl < 10%	Section 21 CCCR[1]	
Chlorine-releasing compounds	available Cl ≥ 10%	Section 20 CCCR[1]	
Quaternary Ammonium Compounds	pH ≤ 0.5 or pH ≥ 13.5	Section 35 CCCR[1]	
Quaternary Ammonium Compounds	0.5 < pH ≤ 2.5 or11.5 ≤ pH < 13.5	Section 36 CCCR[1]	
Quaternary Ammonium Compounds	2.5 < pH < 11.5	Schedule III of the PCP[2] Regulations [Section 27(c)]	Section 36 CCCR[1]
Phenolics and Iodophors	Concentration ≥ 5%	Section 32 CCCR[1]	
Phenolics and Iodophors	Concentration < 5%	Schedule III of the PCP[2] Regulations [Section 27(c)]	Section 32[1]

[1]CCCR:*Consumers Chemicals and Containers Regulations* to the *Hazardous Products Act*.
[2] PCP: Pest Control Products

2) For products intended to be used in food processing plants, the following statement:

- avoid contamination of food.

V) **References:**

a) **Therapeutic Products Programme guidelines: *Disinfectant Drugs*, April 20, 1999.**

Appendix A

SINGLE MEDICINAL INGREDIENTS

Category	Preferred name	Synonym
Quaternary ammonium compounds	Alkyl ethyl benzyl dimethyl ammonium chloride	
	Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride
	Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride
	Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride
	Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium
	Dioctyl dimethyl ammonium chloride	Chloride dioctyl dimethylammonium
	Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethylbenzyl ammonium
	Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium
	Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium
	Octyl decyl dimethyl ammonium chloride	Chloride octyl decyl dimethyl ammonium
	Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
Phenolics	Chloro-ortho-phenylphenol	Chloro-2-phenylphenol
	Chlorophenol	
	Clorophene	o-benzyl-p-chlorophenol
	o-phenylphenol	orthoxenol
	p-phenylphenol	paraxenol
	p-tert-pentylphenol	p-tert-amylphenol
Iodophors	Nonylphenoxy polyethoxyethanol iodine complex	Nonoxynol iodophor A-P-nonylphenyl-omega-hydroxypoly oxyethylene iodine complex
	Polyethoxy polypropoxy polyethoxy ethanol iodine complex	Iodine polyethoxy polypropoxy polyethoxy ethanol
Chlorine releasing compounds	Calcium hypochlorite	
	Sodium hypochlorite	

APPENDIX VIII: CATEGORY IV MONOGRAPH **CONTACT LENS DISINFECTANTS**

I) ***Description:***

This monograph applies to products in liquid or tablet form intended to be used to disinfect contact lenses. The medicinal ingredients, their concentrations and their combinations in Category IV products are restricted to those specified in this monograph. The medicinal ingredients must be identified on product labelling by the names given in Table III (a) (both preferred names and synonyms are considered acceptable).

This monograph does not apply to contact lens disinfectants that contain mercury or a salt or derivative thereof (Section C.01.036 of the *Food and Drugs Regulations*).

II) ***Pharmaceutical Quality:***

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should as a minimum meet Schedule B or equivalent standards. Where no schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:** Manufacturers must meet as a minimum the requirements of Section XIII, Ophthalmic Preparations, of the **Therapeutic Products Programme Guidelines, *Preparation of Drug Identification Number Submissions*, February 1995**, with the exception of the requirements of Section XIII-B Conditions.

III) **Ingredients:**

a) **Single Medicinal ingredients:**

Preferred name	**Synonym**	**Acceptable concentration**
Alkyltriethanolammonium chloride	Quaternium-16	≥ 0.03%
Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride	≥ 0.01%
Chlorhexidine gluconate	Chlorhexidine digluconate	≥ 0.0035%
Hydrogen peroxide	Hydrogen dioxide	≥ 3%
Isopropyl alcohol	Isopropanol	≥ 15%
Polyaminopropyl biguanide		≥ 0.00005%
Polyquaternium-1	Polyquad	≥ 0.001%
Polyhexanide		≥ 0.0001%
Tris (2-hydroxyethyl) tallow ammonium chloride		≥ 0.013%

b) **Combinations of Medicinal Ingredients:**

The following combinations are considered acceptable. The lower limits for use as a single

ingredient also apply when the ingredient is used in combination.

i) Chlorhexidine and EDTA
ii) Alkyltriethanolammonium chloride and EDTA
iii) Chlorhexidine, Polyaminopropyl biguanide and EDTA
iv) Polyquaternium-1 and EDTA

c) **Special notes:**

EDTA may be considered to be a medicinal ingredient if the manufacturer has data available which shows that it is essential for the efficacy of the product. EDTA enhances the activity of a number of medicinal ingredients (e.g., chlorhexidine, benzalkonium chloride, polyquaternium-1, alkyltriethanolammonium chloride) by chelating calcium and magnesium ions.

d) **Nonmedicinal ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation of the particular dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not adversely affect the efficacy or safety of the medicinal ingredients and they must not interfere with tests for the medicinal ingredients or, if present, antimicrobial preservatives.

IV) ***Labelling:***

a) This monograph describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act*, the **Therapeutic Products Programme guidelines: *Disinfectant Drugs*, April 20, 1999** and the ***Guide for the Labelling of Drugs for Human Use*** must also be met. b) Directions for use

i) Indications

All products must indicate:
- disinfectant (or antimicrobial solution), and
- use on a specific type(s) of contact lenses, eg., hard, soft (hydrophillic, tinted, etc.)

ii) Directions for use:

- wash and dry hands thoroughly before handling the lenses;
- preclean the lenses prior to disinfection. (Unless the labelling clearly indicates that the disinfectant or antimicrobial solution is intended to clean the lenses in addition to disinfecting and the directions for use reflect this additional function;
- contact or soaking time required to disinfect the lenses;
- neutralising step, if appropriate (for example, use catalase for products containing hydrogen peroxide);
- rinse procedure after disinfection.

iii) Warnings

- If irritation develops with the use of this product, discontinue use and consult your eye care practitioner;
- Do not touch tip of the bottle to any surface since this may contribute to contamination of the solution;
- Always keep the bottle tightly closed;
- Always use fresh solution and discard after use. Do not reuse solution.

V) ***References:***

a) **Therapeutic Products Programme Guidelines:** ***Disinfectant Drugs***, April 20, 1999.

b) **Therapeutic Products Programme Guidelines:** ***Preparation of Drug Identification Number Submissions***, February 1995.

c) ***Self Medication***, Canadian Pharmaceutical Association, 4th edition, 1992, p.123-147.

d) Martindale, ***The Extra Pharmacopeia***, 1989, ed. by James E.F. Reynolds. p.129.

APPENDIX IX: CATEGORY IV MONOGRAPH

Toilet bowl disinfectant cleaners

I) ***Description:***

This monograph applies to antimicrobial products which are classified as disinfectant drugs and specifically to products which are intended to be used as toilet bowl disinfectant cleaners in health care facilities and food processing plants. The medicinal ingredients and their concentrations in Category IV products are restricted to those specified in this monograph. The medicinal ingredients must be identified on product labelling by the names given in Appendix A of this monograph (both preferred names and synonyms are considered acceptable).

This monograph does not apply to:

a) products with claims for efficacy against:
- spores, as a sterilant, or as a sporicide
- the Tubercle bacilli (Tb), or *Mycobacterium*
- the Human Immunodeficiency Virus (HIV)
- the Hepatitis B Virus (HBV)

II) ***Pharmaceutical Quality:***

All ingredients (medicinal and nonmedicinal) and finished product, should as a minimum meet the specifications of Schedule B or equivalent standard. In the absence of a Schedule B standard, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

III) ***Ingredients:***

a) Single medicinal ingredient categories:

i) Quaternary ammonium compounds
ii) Hydrogen chloride

A list of acceptable single medicinal ingredients for Category IV toilet bowl disinfectant cleaners is provided in Appendix A.

b) **Combinations of Medicinal Ingredients**:

i) Combinations of any of the medicinal ingredients from the same category are permitted provided that the ***total in-use concentration*** of the combined ingredients is at the minimum stated in section IV) d) ii).

ii) Combinations of any of the medicinal ingredients from different categories listed in Appendix A are permitted provided that the ingredient(s) from one of the categories is present at the minimal in-use concentration as stated in section IV) d) ii), and that the ingredients do not interact in a manner that reduces the disinfectant activity.

Note: Phosphoric acid can be considered to be a medicinal ingredient if used in a combination product and if the manufacturer has data available which shows that it is essential for the efficacy of the product.

c) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the efficacy or safety of the medicinal ingredient(s) and they must not interfere with assays and tests for the medicinal ingredients.

IV) ***Labelling:***

a)

This monograph describes those requirements that are specific to toilet bowl disinfectant cleaner drug products for use in healthcare facilities and food processing plants. Other requirements described in the *Regulations to the Food and Drugs Act* and in the **Therapeutic Products Programme guidelines: *Disinfectant Drugs*** must also be met.

b) **Unacceptable claims:**

Statements such as non-toxic, safe, non-caustic, harmless, etc. are not considered appropriate for disinfectant drugs.

c) **Indications**:

All products must indicate:

i) for use in a health care facility (e.g., hospitals, dental clinic, nursing homes) or in food processing plants;

ii) one or more of the following as applicable to the product:

1) disinfectant / disinfectant cleaner

2) kills bacteria (bactericide)
3) kills viruses (virucide)
4) kills fungi (fungicide)
5) kills germs (germicide)

d) **Directions for Use**

i) For all products complete directions for use as a toilet bowl disinfectant cleaner including:

- specific amount/volume of disinfectant to be used
- mode of application;
- a contact time of at least 10 minutes followed by a flush of the toilet;

ii) **In-use solution concentrations**

1) Quaternary ammonium compounds ≥ 450 ppm
2) Hydrogen choride ≥ 9.5%

iii) **Warnings and First Aid Information**

For all products, should correspond to those described in the *Consumer Chemicals and Containers Regulations* to the *Hazardous Products Act* or the *Pest Control Products Regulations* as indicated in the following table:

CATEGORY	CRITERIA	REFERENCE	ALTERNATIVE
Hydrogen Chloride or Phosphoric acid	Conc. ≥ 10%	Section 24 CCCR[1]	Schedule III of the PCP[2] Regulations [Section 27(c)]
Hydrogen Chloride or Phosphoric acid	5% ≤ Conc. < 10%	Section 25 CCCR[1]	
Hydrogen Chloride or Phosphoric acid	1% ≤ Conc. < 5%	Section 26 CCCR[1]	
Quaternary Ammonium Compounds	pH ≤ 0.5 or pH ≥ 13.5	Section 35 CCCR[1]	
Quaternary Ammonium Compounds	0.5 < pH ≤ 2.5 or 11.5 ≤ pH < 13.5	Section 36 CCCR[1]	
Quaternary Ammonium Compounds	2.5 < pH < 11.5	Schedule III of the PCP[2] Regulations [Section 27 (c)]	Section 36 CCCR[1]

[1] CCCR: *Consumers Chemicals and Containers Regulations* to the *Hazardous Products Act*. [2] PCP: Pest Control Products

(V) ***References:***

a) **Therapeutic Products Programme guidelines**: ***Disinfectant Drugs*, April 20, 1999**.

Appendix A

SINGLE MEDICINAL INGREDIENTS

Category	Preferred name	Synonym
Quaternary ammonium compounds	Alkyl ethyl benzyl dimethyl ammonium chloride	
	Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride
	Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride
	Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride
	Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium
	Dioctyl dimethyl ammonium chloride	Chloride dioctyl dimethylammonium
	Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethylbenzyl ammonium
	Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium
	Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium
	Octyl decyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
	Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
Inorganic Acid	Hydrogen chloride	Hydrochloric acid

APPENDIX X:

LABELLING STANDARD
QUATERNARY AMMONIUM COMPOUNDS FOR USE AGAINST HIV

I) ***Description:***

This labelling standard applies to antimicrobial products which are classified as disinfectant drugs and specifically to products which (1) contain quaternary ammonium compounds as medicinal ingredients (2) are intended to be used as environmental hard surface disinfectants in health care facilities and (3) have claims for efficacy against the human immunodeficiency virus (HIV). The medicinal ingredients and their concentrations in Category III products are restricted to those specified in this standard. The medicinal ingredients must be identified on product labelling by the names given in Appendix A of this monograph (both preferred names and synonyms are considered acceptable).

This monograph does not apply to:

a) disinfectant products to be used on medical devices or instruments, including contact lenses

(refer to Category IV product monograph, ***Contact Lens Disinfectants***);

b) products with claims for efficacy against;
- spores, as a sterilant, or as a sporicide
- the Tubercle bacilli (Tb), or *Mycobacterium*
- the Hepatitis B Virus (HBV)

II) ***Pharmaceutical Quality:***

a) All ingredients (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the specifications of Schedule B or equivalent standard. In the absence of a Schedule B standard, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

III) ***Ingredients:***

a) **Single medicinal ingredients:**

This standard applies only to those products which contain quaternary ammonium compounds as their medicinal ingredients.

A list of acceptable single medicinal ingredients for this category of products is provided in Appendix A.

b) **Combinations of Medicinal Ingredients:**

Combinations of any of the medicinal ingredients from the same category are permitted provided that the ***total in-use concentration*** of the combined ingredients is at the minimum stated in section IV) d) **iii)**.

c) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the efficacy or safety of the medicinal ingredient(s) and they must not interfere with assays and tests for the medicinal ingredients.

IV) ***Labelling:***

a)

This standard describes those requirements that are specific to hard surface disinfectant drug products. Other requirements described in the***Food and Drugs Act and Regulations*** and in the **Therapeutic Products Programme guidelines**: ***Disinfectant Drugs***, must also be met.

b) **Unacceptable claims:**

Statements such as non-toxic, safe, non-caustic, harmless, etc. are not considered appropriate for disinfectant drugs.

c) **Indications**:

For all products, the labelling must indicate:

i) **either or both of the following statements:**

- for use in a health care facility (e.g, hospitals, dental clinic, nursing homes)
- for use in a health care facility **and** in premises where food is manufactured, processed or kept; and

ii) one or more of the following as applicable to the product:

- disinfectant / disinfectant cleaner
- kills bacteria (bactericide)
- kills viruses (virucide)
- kills fungi (fungicide)
- kills germs (germicide)

d) **Directions for Use:**

i) For all products, the labelling should provide complete use directions as an environmental surface disinfectant including:

- types of surfaces (e.g, floors, walls, countertops);
- specific instructions for the preparation of the in-use dilution in metric units of measure;
- mode of application;
- a contact time of 10 minutes if the product is to be rinsed or wiped off;

ii) For all products to be used in a food processing establishment, the labelling should include a statement to the effect that:

- "all surfaces that come into contact with food are to be rinsed with potable water after disinfection".

iii) In-use solution concentrations:

1) $\geq$ 450 ppm	For general disinfection of environmental surfaces

2) ≥ 800 ppm	For disinfection of surfaces in those settings where the HIV is expected to be encountered, such as settings where contamination by blood or body fluids is likely.

iv) Warnings and First Aid Information:

1) For all products, should correspond to those described in the *Consumers Chemicals and Containers Regulations* to the *Hazardous Products Act* or the *Pest Control Products Regulations* as indicated in the following table:

CRITERIA	REFERENCE	ALTERNATIVE
pH ≤ 0.5 or pH ≥ 13.5	Section 35 CCCR[1]	☒
0.5 < pH ≤ 2.5 or 11.5 ≤ pH < 13.5	Section 36 CCCR[1]	☒
2.5 < pH < 11.5	Schedule III of the PCP[2] Regulations and Section 27(c)	Section 36 CCCR[1]
[1] CCCR: Consumers Chemicals and Containers Regulations [2] PCP: Pest Control Products		

2) For products intended to be used in food processing plants, the following statement should be indicated:

- "avoid contamination of food"

v) Additional Labelling Requirements:

The following additional labelling criteria must be included:

1. There should be no reference to the treatment or prevention of "AIDS", a schedule A disease, on the labelling. The term "HIV" is acceptable, but should also be identified as "Human Immunodeficiency Virus".

2. Directions for use should indicate that the product is intended for use against HIV only in those settings where the virus would be expected to be encountered, such as settings where contamination by blood or body fluids is likely.

3. Directions for use should also provide specific decontamination procedures, including:

    i. The need for surfaces to be cleaned prior to disinfection should be identified.

2. Personnel that clean items soiled with blood or body fluids should be cautioned to wear appropriate barrier protection such as disposable gloves, gowns, and masks, etc..

3. Directions for the disposal of cleaning materials and waste should be specified, e.g. autoclave soiled materials.

4. Directions for proper dilution and application of the disinfectant, including appropriate contact times, should be given.

V) ***References:***

a) **Therapeutic Products Programme guidelines**: ***Disinfectant Drugs*, April 20, 1999.**

Appendix A

Quaternary Ammonium Compounds
Single Medicinal Ingredients

Preferred name	Synonym
Alkyl ethyl benzyl dimethyl ammonium chloride	
Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride
Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride
Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride
Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium
Dioctyl dimethyl ammonium chloride	Chloride dioctyl dimethylammonium
Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethylbenzyl ammonium
Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium
Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium
Octyl decyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium

APPENDIX XI: LABELLING STANDARD
ETHYLENE OXIDE GASEOUS STERILANTS

I. ***Description:***

This labelling standard applies to ethylene oxide products labelled for use as gaseous sterilants for medical instruments/devices. This labelling standard does not apply to *any other liquid and gaseous drug products* to be used as sterilants for medical instruments/devices.

2. ***Pharmaceutical Quality:***

    a. All ingredients (medicinal and nonmedicinal) and finished product, should, as a minimum, meet the specifications described in the publications referred to in Schedule B to the *Food and Drugs Act* or equivalent standards. In the absence of a Schedule B standard, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

    2. **Special Notes:**
        - i) Validation of sterilization and sterility assurance should be conducted according to the specifications in *The United States Pharmacopoeia, USP 23, NF 18*, Chapter <1211>.
        - ii) The validation process should involve biological indicators prepared as detailed in *The United States Pharmacopoeia, USP 23, NF 18,* pages 202-204 and Chapter <1035>.

3. ***Ingredients:***

    a. **Single medicinal ingredient:**

    Ethylene oxide 10-100%

    2. **Nonmedicinal Ingredients:**
    Nonmedicinal ingredients must be restricted to those substances necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the efficacy or safety of the ethylene oxide and they must not interfere with assays and tests for the medicinal ingredients.

4. ***Labelling:***

    a. This labelling standard describes those requirements that are specific for this type of product. Other requirements described in the *Food and Drugs Act and Regulations* and in the **Therapeutic Products Programme guideline**: ***Disinfectant Drugs***, must also be met.

    2. **Unacceptable claims:**

    Statements such as non-toxic, safe, non-caustic, harmless, etc. are not considered appropriate for this type of product.

    3. **Indications**:

    For all products the labelling must indicate:

        i. For use as a sterilant for medical instruments/devices in a health care facility (e.g, hospitals, dental clinic, etc.) in a sterilizer (model and type must be indicated).

4. **Directions for Use**

   i. For all products complete directions for use as a gaseous sterilant **should be specified**, including:
   - types of instruments (e.g, implants, surgical instruments, laparoscopes, burs, needles, etc.);
   - adequate wrapping procedures;
   - adequate load procedures;
   - specific precleaning procedures;
   - specific instructions for the safe and effective use of the product including specific cycle times, temperature, humidity, pressure of the ethylene oxide in the exposure chamber, adequate ventilation/aeration procedures, etc.
   - adequate in process validation procedure (i.e., use of biological indicators) as indicated in Section II) **b)** ii).

   2. A reference to an operator manual is considered acceptable provided that all the information listed in Section IV) **d)** i) is adequately addressed in the manual.

   3. **Warnings:**

      For all products, the label must indicate the following symbols and statements:

      - the warning statement DANGER associated with the appropriate symbol

      - the hazard symbol, signal word and hazard statements for pressurized containers as described in Sections A.01.060.1 to A.01.062 of the *Food and Drugs Regulations*

      - ETHYLENE OXIDE VAPOUR IS HARMFUL

      - Avoid breathing vapours

      - Keep container closed

      - May cause burns

      - Avoid contact with skin or eyes

      - This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical use areas.

   4. First aid and toxicological information:

      For all products, the labelling must indicate the following statements:

- In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes;

- **For contact with eyes,** call a physician;

- Remove and wash contaminated clothing before reuse;

- If ethylene oxide was swallowed, drink egg whites, gelatin solution or, if these are not available, drink large quantities of water. Call a physician.

5. ***References:***

a. **Therapeutic Products Programme guidelines**: ***Disinfectant Drugs*, April 20, 1999.**

2. ***The United States Pharmacopoeia***, USP 23, NF 18, 1995.

APPENDIX XII:

Standard Labels for Quaternary Ammonium Hard Surface Disinfectant Products Requiring Registration Pursuant to the Pest Control Products Act

The purpose of this document is to outline the proposed labelling standard for Quaternary Ammonium only based products for use as disinfectants or sanitizers on hard non-porous surfaces in schools, households, industry and agriculture.

1. ***Introduction***

Quaternary ammonium (QA) compounds are contained in a wide variety of commercial and domestic hard surface disinfectant/sanitizer products. Registration of new or modified formulations in Canada pursuant to the Pest Control Products Act currently requires the evaluation of six acute toxicity studies (acute oral, dermal, and inhalation studies, eye and dermal irritation studies and a dermal sensitization study) and efficacy studies. This document proposes standard labels for certain products that would eliminate the submission and evaluation of toxicology and efficacy data in support of registration provided that labelling criteria are met.

a. The registrant would still be required to submit the following information for evaluation prior to issuing a registration number:

1. an application for new or amended registration;
2. a product specification form;
3. five copies of the draft Standard Label;
4. a letter of confirmation of source of supply from the manufacturer or supplier of each active ingredient and
5. cheque made out to the receiver general of Canada for the

appropriate fee.

2. All products outlined in this document must be manufactured using a registered source(s) of the active ingredient(s) listed in Table 2. The product may contain combinations of these active ingredients but may not contain any not listed in Table 2. **Please contact the PMRA for information related to registered sources of active ingredient.**

3. Maximum total percent guarantee will not exceed 15% percent for domestic products registered utilizing standard labelling. The in use concentration of active ingredient for any product including ready to use sprays must be less than 1% for the purposes of this standard label.

4. Registrants are responsible for using formulants that are not of toxicological concern and the responsibility for providing information on their safety will rest with the registrants using reputable sources such as scientific literature and MSD sheets.

5. NOTE: This standard label approach is not intended for uses other than those specified in the labelling instructions. Uses such as air duct disinfection, air sanitization, fogging application, high pressure (greater than 500 psi) sprayers, humidifiers and treatment of crops such as vegetables are not included in these standard labels. These uses will continue to require safety and efficacy reviews.

6. All domestic class spray products having a pH below 2 or above 11.5, are required to have a child resistant container. Registrants are also encouraged to use child resistant containers for non-spray domestic products that have a total QA greater or equal to 1% or a pH below 2 or above 11.5.

7. This proposal for a standard label for hard surface disinfectant uses of quaternary ammonium compounds is intended as a pilot project. It is recognized that considerable responsibility rests with the registrant and as such, submissions received under this proposal will be periodically audited for their compliance with the terms and conditions of this Regulatory Proposal. After a one year pilot period, an assessment of the adequacy of this standard label approach will be conducted.

2. ***Definitions***

For purposes of this document the following definitions will apply:

a. *Non-spray Products*

- Ready-to-use or concentrated liquids for application with mop and pail, sponge or swab.

- Liquid concentrated products to be further diluted for spray application.

2. *Respirable spray products*

   - Products formulated in pressurized cans other than those producing foam.

3. *Non-respirable spray products*
   - Products formulated in finger trigger containers, finger pump containers, foam products in pressurized cans.

   - Products requiring use dilution and applied using low pressure (less than 40 psi) canisters such as backpack sprayers, and wand sprayers.

3. *General Instructions For Standard Labels*

Registrants are reminded of several points regarding the use of standard labels:

a. The text appearing on the standard labels represents minimum labelling requirements for hard surface disinfectants. Registrants have the option of placing additional information such as distinctive trade marks and logos on their own labels.

2. The model labels may be used for commercial and domestic class disinfectant products.

3. Display panels of control products where the primary purpose is not for controlling or preventing bacteria e.g. cleaner disinfectant, may be modified as outlined in section 30 of the Pest Control Products Regulations.

4. Any environmental label claims must be consistent with DIR 96-02 "Environmental Label Claims and Advertising of Pest Control Products" March 15, 1996.

5. Statements indicated in quotation marks within this document must be included on the label as written.

6. Registrants have the option of submitting efficacy and/or toxicology studies if they feel the standard label does not reflect the properties of their product. Products that do not satisfy all criteria indicated in this document may utilize the standard label format but will continue to be assessed on a case-by-case basis.

4. *Label Instructions*

As outlined in section 27 of the Pest Control Products Regulations the following sections must appear on the labels of registered Pest Control Products

A. **Primary Display Panel**

The following 8 items (a through h) must appear on the primary display panel of a hard surface disinfectant.

a. The name of the control product containing a description of the physical form and the purpose of the product. Products must specify one or more of the following claims: Disinfectant, Sanitizer, Controls Bacteria, Eliminates Bacteria, Bactericide, Biocidal, or Germicidal.

2. The product class designation shown in capital letters i.e. **DOMESTIC, COMMERCIAL, INDUSTRIAL, AGRICULTURAL.**

3. Information respecting the nature and degree of hazard identified by the appropriate precautionary symbols and signal words selected from Schedule III of the Pest Control Products Regulations. Hazard symbols and signal words relate to the systemic, irritation (eyes and skin) and skin sensitization hazard of the QA-disinfectants. To determine the appropriate symbol and signal words the registrant should refer to Table 1 below.

TABLE I: Standard Hazard Information

Product Type	Condition	Signal Words	Symbols
All	if pH < 2 or pH > 11.5 (regardless of quaternary ammonium concentration)	DANGER - CORROSIVE TO EYES & SKIN	
	if 2 ≤ pH ≤ 11.5 and [Quats][a] <1%	CAUTION - IRRITATING TO EYES & SKIN	No symbol
	if 2 ≤ pH ≤ 11.5 and [Quats] 1%	DANGER - CORROSIVE TO EYES & SKIN	No symbol
	if product contains a	POTENTIAL SKIN	No symbol
Spray(ready-to-use)	if pH < 2 or pH > 11.5 (regardless of aerosol size)	DANGER POISON	
	if: 2 ≤ pH ≤ 11.5 and respirable aerosol is generated (e.g. pressurized spray cans)	CAUTION POISON	

Liquid (ready-to-use or concentrate)	If: [Quat] < 8%	Poison symbol and signal words are not required	
	if: 8% ≤ [Quats] ≤ 40%	CAUTION POISON	
	if [Quats] >40%	DANGER POISON	
Pressurized	All	CAUTION EXPLOSIVE	

[a] **Total concentration of all quaternary ammonium compounds in the product. NOTE:** Where more than one precautionary symbol is required on the label, only the most severe signal word is required, and all of the hazard identifying words.

☒ d. A statement directing the user to read the label in the following form. **"READ THE LABEL BEFORE USING"**

☒ e. A guarantee statement set out as: **"GUARANTEE:"** Common name of the active ingredient (See Table 2) and the contents of the active expressed as a percentage.

The actives may be present in the formulation singly or in combination with any other active specified in Table 1.

☒ f. The registration number for the product. **"REGISTRATION NO. 00000 PEST CONTROL PRODUCTS ACT"**. On domestic class products this statement may be written as: **"REG. NO. 00000 P.C.P. ACT"**

☒ g. Declaration of **"NET CONTENTS:"**.

☒ h. Name and postal address of the registrant, and name and address of the Canadian agent, if applicable.

B. Secondary Display Panel

The following 6 items (i through n) are required on the secondary display panel:

i. *DIRECTIONS FOR USE:*

All products must have use instructions complete with a description of the application method. The following should be included:

- An indication that heavily soiled surfaces should be precleaned prior to treatment.
- An indication of the types of surfaces to be treated (non-porous hard surfaces such as floors, walls, counter tops, chairs, bathroom fixtures, garbage pails).
- Specific dilution instruction for the product resulting in a concentration of the active ingredient greater than or equal to 450 ppm for all disinfectant claims.
- Clear description of the method of application ie. mop, sponge, cloth, trigger coarse spray.
- Indication of contact time (10 minutes for disinfection, 30 seconds for sanitization)
- Domestic products with use instructions for kitchens, stoves, countertops, where there is the potential for food contamination, must include potable water rinse instructions.

The following are some examples of acceptable use instructions:

Domestic Spray:
1) Shake well. Hold can 15 to 20 cm from surface. Press button and cover with foam. Leave for 10 minutes to disinfect.
2) Wipe off with clean cloth or sponge.
3) For stubborn stains, allow foam to remain on surfaces longer.

Domestic Disinfectant Cleaner (Mop and Pail):
For disinfection of hard, non-porous surfaces, such as floors, shower stalls, diaper pails, garbage cans. Preclean surfaces with a solution of .....ml per litre of water. Apply disinfectant solution of .....ml per litre of water. Allow surfaces to remain wet for 10 minutes, then remove excess liquid. Rinse with clean water. Prepare a fresh solution for each use.

Commercial Disinfectant Cleaner:
Uses: Floors, walls, empty basins, showers, garbage cans, lavatory fixtures and other hard, non-porous surfaces.
Application: Remove gross filth and heavy soil deposits. Preclean all surfaces prior to disinfection.
To Disinfect: Thoroughly wet surfaces. Use....ml per litre of water. Allow treated surfaces to remain wet for a minimum of 10 minutes in a single application . Can be applied with a mop, sponge, or cloth as well as coarse (trigger) spray. Prepare a fresh solution for each use then discard.
To Sanitize: For use on hard non-porous surfaces such as counter tops. Preclean all surfaces prior to sanitizing. Use ..... ml per litre of water for a minimum contact time of .... seconds. Can be applied by mop, sponge, or cloth as well as by coarse (trigger) spray.

Claims to control specific organisms may be included on Commercial products.

For general disinfectants, Salmonella choleraesuis, Staphylococcus aureus, and Escherichia coli may be claimed. These claims should be accompanied by a reference on the label to an appropriate test protocol ie." This product has been shown to be effective against the following organisms by AOAC Use Dilution Method:".

Claims to control organisms other than the above three bacteria will continue to be assessed on a case-by-case basis. The registration of products with specific viruses, fungi, and bacteria claims will require appropriate efficacy data.

j. i. **"PRECAUTIONS** - KEEP OUT OF REACH OF CHILDREN. HARMFUL IF SWALLOWED OR INHALED. DO NOT SWALLOW. DO NOT INHALE AEROSOLS OR VAPOURS. MAY IRRITATE EYES OR SKIN. DO NOT GETINEYES OR SKIN OR CLOTHING. AVOID CONTAMINATION OF FOOD."

2. Add the appropriate personal protective equipment(PPE) statements to the PRECAUTIONS section based on the relevant criteria listed below.

NOTE: PPE statements may require further revision once the Interim Policy on Eye Irritation is finalized.

1. **PPE Statements for Domestic Products**

PPE is not required for the following:
-product has total QA less than 1% and the pH is between 2 and 11.5

The phrase "Wear rubber gloves when handling the product." should be added if both of the following conditions are met:
-product is mop/wipe, trigger or pump spray and
-total QA greater or equal to 1% or the pH value is below 2 or above 11.5

2. **PPE Statements for Commercial Products**

PPE is not required if both of the following conditions are met:
-product is mop/wipe, trigger, pump or pressurized spray and
-total QA less than 1% and the pH is between 2 and 11.5

The phrase "Wear goggles when applying the product." should be added if both of the following conditions are met:
-product is any non-foaming pressurized spray and
-pH is below 2 or above 11.5

The phrase "Wear chemical resistant gloves and goggles when diluting the product." should be added if both of the following conditions are met:

-product is mop/wipe type and
-total QA greater or equal to 1% or the pH is below 2 or above 11.5

The phrase "Wear chemical resistant gloves and goggles when diluting the product; wear goggles when applying as a spray." should be added if both of the following conditions are met:
-product is a liquid that requires dilution for trigger or pump spray use
-total QA greater or equal to 1% or the pH is below 2 or above 11.5

The phrase "Wear long sleeve shirt, long pants and chemical resistant gloves when handling the product; wear goggles or face shield when diluting or when applying as a spray." should be added for the following:
-low pressure canister spray products

Note: The more stringent PPE statement should be used for those products that have multiple methods of application on the label.

k. **"DISPOSAL"**

Select an appropriate statement from the following recommended texts:

i. Commercial class products packaged in volumes greater than or equal to 20 Litres:

"1. Rinse the emptied container thoroughly and add the rinsings to the treatment site.
2. Follow provincial instructions for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the Provincial Regulatory Agency or the Manufacturer."

2. Domestic products and Commercial class products in volumes less than 20 Litres

"For information on the disposal of unused, unwanted products and the cleanup of spills, contact your municipality or the Provincial Regulatory Agency."

3. Small size pressurized disinfectants

"This container may be recycled in communities where aerosol can recycling is available. Before offering for recycling, empty the can by using the product according to the label. (DO NOT PUNCTURE!) If recycling is not available, contact your municipality or provincial Ministry of Environment for disposal information."

l. " **FIRST AID INSTRUCTIONS:**"

" If splashed in eyes or on skin, flush thoroughly with water for 15 minutes. For eye contact, get medical attention IMMEDIATELY. If on clothes, remove clothes immediately. If breathed in, move person to fresh air. If swallowed, drink two or three glasses of milk or water. Do not induce vomiting. Call a physician or the Poison Control Centre IMMEDIATELY."

m. " **TOXICOLOGICAL INFORMATION:**"

" Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed."

n. "**NOTICE TO USER:**"

"This control product is to be used only in accordance with the directions on this label. It is an offence under the Pest Control Products Act to use a control product under unsafe conditions."

TABLE 2 ACTIVE INGREDIENTS

Active Code	Common Name
QAB	N-Alkyl (25% C_{12}, 60% C_{14}, 15% C_{16}) Dimethyl Benzyl Ammonium Chloride
QAC	N-Alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) Dimethyl Benzyl Ammonium Chloride
QAE	N-Alkyl (50% C_{12}, 30% C_{14}, 17% C_{16}, 3% C_{18}) Dimethyl Ethyl Benzyl Ammonium Chloride
QAF	N-Alkyl (68% C_{12}, 32% C_{14}) Dimethyl Ethyl Benzyl Ammonium Chloride
QAK	Didecyl Dimethyl Ammonium Chloride
QAL	N-Alkyl (5% C_{12}, 60% C_{14}, 30% C_{16}, 5% C_{18}) Dimethyl Benzyl Ammonium Chloride
QAO	N-Alkyl (1% C_{8}, 1% C_{10}, 67% C_{12}, 25% C_{14}, 7% C_{16}, 1% C_{18}) Dimethyl Benzyl Ammonium Chloride
QAQ	N-Alkyl (5% C_{5-18}, 61% C_{12}, 23% C_{14}, 11% C_{16}) Dimethyl Benzyl Ammonium Chloride

QDE	Dioctyl Dimethyl Ammonium Chloride
QDF	Octyl Decyl Dimethyl Ammonium Chloride

APPENDIX 1

[SAMPLE LABEL OF PRINCIPAL DISPLAY PANEL]

YOUR BRAND DESIGNATION
LIQUID DISINFECTANT
FOR HARD SURFACES
(section a)

COMMERCIAL
(section b)

REGISTRATION NO. 00000 PEST CONTROL PRODUCTS ACT
(section f)

GUARANTEE: N-Alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) Dimethyl Benzyl Ammonium Chloride.....10%
(section e)

CAUTION

POISON

DANGER - CORROSIVE TO EYES AND SKIN
(section c)

NET CONTENTS: 20 Litres
(section g)

READ THE LABEL BEFORE USING
(section d)

Your Company, Your street address (or P.O. Box No.)
Your City, Your Province, Postal Code
(section h)

[Sample label Secondary Panel]

DIRECTIONS FOR USE: (Section I)

Uses: Floors, walls, empty basins, showers, garbage cans, lavatory fixtures and other hard, non-porous surfaces.

Application: Remove gross filth and heavy soil deposits. Preclean all surfaces prior to disinfection.

To Disinfect: Thoroughly wet surfaces. Use....ml per litre of water. Allow treated surfaces to remain wet for a minimum of 10 minutes in a single application . Can be applied with a mop, sponge, or cloth as well as coarse (trigger) spray. Prepare a fresh solution for each use then discard.

At this dilution the product has been shown to be effective against the following organisms by AOAC Use Dilution Method:

Salmonella choleraesuis,
Staphylococcus aureus,
Escherichia coli

To Sanitize: For use on hard non-porous surfaces such as counter tops. Preclean all surfaces prior to sanitizing. Use ..... ml per litre of water for a minimum contact time of .... seconds. Can be applied by mop, sponge, or cloth as well as by coarse (trigger) spray.

PRECAUTIONS: (Section j)

KEEP OUT OF REACH OF CHILDREN. HARMFUL IF SWALLOWED OR INHALED. DO NOT SWALLOW. DO NOT INHALE AEROSOLS OR VAPOURS. MAY IRRITATE EYES OR SKIN. DO NOT GET IN EYES, ON SKIN OR CLOTHING. AVOID CONTAMINATION OF FOOD. Wear chemical resistant gloves and goggles when diluting the product; wear goggles when applying as a spray.

FIRST AID INSTRUCTIONS: (Section k)

If splashed in eyes or on skin, flush thoroughly with water for 15 minutes. For eye contact, get medical attention IMMEDIATELY. If on clothes, remove clothes immediately. If breathed in, move person to fresh air. If swallowed, drink two or three glasses of milk or water. Do not induce vomiting. Call a physician or the Poison Control Centre IMMEDIATELY.

TOXICOLOGICAL INFORMATION: (Section l)

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DISPOSAL: (Section j)

1. Rinse the emptied container thoroughly and add the rinsings to the treatment site.
2. Follow provincial instructions for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the Provincial Regulatory Agency or the Manufacturer.

NOTICE TO USER: (Section m)

This control product is to be used only in accordance with the directions on this label. It is an offence under the Pest Control Products Act to use a control product under unsafe conditions."

[SAMPLE LABEL OF PRINCIPAL DISPLAY PANEL]

YOUR BRAND DESIGNATION
LIQUID DISINFECTANT
FOR HARD SURFACES
(section a)

DOMESTIC
(section b)

REG. NO. 00000 P.C.P. ACT
(section f)

GUARANTEE:
N-Alkyl (5%C_{12}, 60% C_{14}, 30% C_{16}, 5% C_{18}) Dimethyl Benzyl AmmoniumChloride.....1.5%
N-Alkyl (68%C_{12}, 32%C_{14}) Dimethyl Benzyl Ammonium Chloride.....1.5%

(section e)

DANGER- CORROSIVE TO EYES AND SKIN

(section c)

NET CONTENTS: 750 mL
(section g)

READ THE LABEL BEFORE USING
(section d)

Your Company, Your street address (or P.O. Box No.)
Your City, Your Province, Postal Code
(section h)

[Sample label Secondary Panel]

DIRECTIONS FOR USE: (Section I)

For disinfection of hard, non-porous surfaces, such as floors, shower stalls, diaper pails, garbage cans. Preclean surfaces with a solution of .....ml per litre of water. Apply disinfectant solution of .....ml per litre of water. Allow surfaces to remain wet for 10 minutes, then remove excess liquid. Rinse with clean water. Prepare a fresh solution for each use.

PRECAUTIONS: (Section j)

KEEP OUT OF REACH OF CHILDREN. HARMFUL IF SWALLOWED OR INHALED. DO NOT SWALLOW. DO NOT INHALE AEROSOLS OR VAPOURS. MAY IRRITATE EYES OR SKIN. DO NOT GET IN EYES, ON SKIN OR CLOTHING. AVOID CONTAMINATION OF FOOD. Wear rubber gloves when handling the product

FIRST AID INSTRUCTIONS: (Section k)

If splashed in eyes or on skin, flush thoroughly with water for 15 minutes. For eye contact, get medical attention IMMEDIATELY. If on clothes, remove clothes immediately. If breathed in, move person to fresh air. If swallowed, drink two or three glasses of milk or water. Do not induce vomiting. Call a physician or the Poison Control Centre IMMEDIATELY.

TOXICOLOGICAL INFORMATION: (Section l)

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DISPOSAL: (Section j)

For information on the disposal of unused, unwanted products and the cleanup of spills, contact your municipality or the Provincial Regulatory Agency.

APPENDIX XIII: LABELLING GUIDE
Sanitisers/cleaners

I. ***Description:***

This guide applies to antimicrobial products which are classified as sanitisers/cleaners and specifically to products which are intended to be used as environmental sanitisers/cleaners in food processing plants. The active ingredients and their concentrations in these products are restricted to those specified in this guide. The active ingredients must be identified on product labelling by the names given in Appendix A of this guide (both preferred names and synonyms are considered acceptable).

This guide does not apply to:

a. disinfectant products to be used on environmental surfaces and other inanimate objects for the mitigation or prevention of disease in humans or animals in food processing plants and health care facilities. For these types of products, consult the **Therapeutic Products Programme guidelines: *Disinfectant Drugs***, for further information.
b. disinfectant products to be used on medical devices or instruments, including contact lenses. For these types of products, consult the **Therapeutic Products Programme guidelines: *Disinfectant Drugs***, for further information.

Notes:

- **Antimicrobial products which are intended for use solely as sanitisers/cleaners do not require a Drug Identification Number (DIN) prior to being sold on the market.**
- **If product labelling does not meet the criteria established in this guide, applicants are referred to the Chemical Health Hazard Assessment Division, Bureau of Chemical Safety, Food Directorate.**

II. ***Ingredients:***

a. **Active ingredient categories:**

i. Iodophors
ii. Chlorine releasing compounds
iii. Quaternary ammonium compounds
iv. Anionic surfactants
v. Hydrogen peroxide, peracetic acid, acetic acid solutions

A list of acceptable single active ingredients for sanitisers/cleaners is provided in Appendix A.

b. **Combinations of Active Ingredients:**

i. Combinations of any of the active ingredients from the same category are permitted.

c. **Nonactive Ingredients:**

Nonactive ingredients must be restricted to those substances necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the toxicity or safety of the active ingredient(s) and they must not interfere with assays and tests for the active ingredients. A list of acceptable nonactive ingredients for sanitisers/cleaners is provided in Appendix B.

III. ***Labelling:***

This section describes those requirements that are specific to sanitizing products.

a. **Unacceptable claims:**

Statements such as non-toxic, safe, harmless, etc. are not considered appropriate for sanitisers/cleaners.

b. **Indications:**

All products must indicate **the following statements:**

i. for use in a food processing plant
ii. intended for use as a sanitiser/cleaner or equivalent
iii. rinse with potable water for food contact surfaces where required

c. **Directions for Use:**

i. For all products, complete directions for use as a sanitiser/cleaner for environmental surfaces must be specified, including:

- types of surfaces (e.g, floors, walls, countertops);
- specific instructions for the preparation of the in-use dilution in metric units of measure;
- mode of application;
- a contact time of 3 minutes if the product is to be rinsed off;
- avoid contamination of food

ii. **In-use solution concentrations with no rinse necessary:**

1) Iodophors	$\leq$ 25 ppm
2) Chlorine	$\leq$ 200 ppm
3) Quaternary ammonium compounds	$\leq$ 200 ppm
4) Anionic surfactants:	
- Dodecyl benzene sulfonic acid and its sodium salts	$\leq$ 200 ppm
- Sulfonated oleic acid, sodium salt	$\leq$ 300 ppm
5) Hydrogen peroxide, peracetic acid, acetic acid solutions	$\leq$ 1100 ppm H_2O_2
Nonactive ingredients as listed in Appendix B	

iii) **In-use solution concentrations with rinse necessary:**

1) Iodophors	> 25 ppm
2) Chlorine	> 200 ppm
3) Quaternary ammonium compounds	> 200 ppm
4) Anionic surfactants:	
- Dodecyl benzene sulfonic acid and its sodium salts	> 200 ppm
- Sulfonated oleic acid, sodium salt	> 300 ppm
5) Hydrogen peroxide, peracetic acid, acetic acid solutions	> 1100 ppm H_2O_2
Nonactive ingredients as listed in Appendix B	

IV. **Warnings and First Aid Information:**

a. For all products, should correspond to those described in the *Consumer Chemicals and Containers Regulations*, to the *Hazardous Products Act* or the *Pest Control Products Regulations* as indicated in the following table:

CATEGORY	CRITERIA	REFERENCE	ALTERNATIVE
Chlorine-releasing compounds	available Cl < 1%	Section 22 CCCR[1]	PCP[2] Regulations: - Schedule III -Section 27 (c)
Chlorine-releasing compounds	1% ≤ available Cl < 4%	Section 22 CCCR[1]	PCP[2] Regulations: - Schedule III -Section 27 (c)
Chlorine-releasing compounds	4% ≤ available Cl < 10%	Section 21 CCCR[1]	PCP[2] Regulations: - Schedule III -Section 27 (c)
Chlorine-releasing compounds	available Cl ≥ 10%	Section 20 CCCR[1]	PCP[2] Regulations: - Schedule III -Section 27 (c)
Quaternary Ammonium Compounds	pH ≤ 0.5 or pH ≥ 13.5	Section 35 CCCR[1]	
Quaternary Ammonium Compounds	0.5 < pH ≤ 2.5 or 11.5 ≤ pH < 13.5	Section 36 CCCR[1]	
Quaternary Ammonium Compounds	2.5 < pH < 11.5	Schedule III of the PCP[2] Regulations [Section 27 (c)]	Section 36 CCCR[1]
Iodophors	Concentration < 5%	Schedule III of the PCP[2] Regulations [Section 27 (c)]	Section 32[1]
Iodophors	Concentration ≥ 5%	Section 32 CCCR[1]	
Dodecylbenzene sulfonic acid	1.9 ≤ pH ≤ 2.2		

[1] CCCR: *Consumers Chemicals and Containers Regulations* to the *Hazardous Products Act*.
[2] PCP: Pest Control Products

Note: Applicants are referred to Part 7 of the Pest Control Product Registration Handbook, which expands upon the precautionary symbols and signal words contained in Schedule III of the *Pest Control Products Act*.

V) *References:*

a. **Therapeutic Products Programme guidelines: *Disinfectant Drugs*, April 20, 1999.**

Appendix A

Sanitisers / Cleaners

Active Ingredients

Category	Preferred name	Synonym
Quaternary ammonium compounds	Alkyl ethyl benzyl dimethyl ammonium chloride	
	Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride
	Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride
	Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride
	Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium
	Dioctyl dimethyl ammonium chloride	Chloride dioctyl dimethylammonium
	Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethylbenzyl ammonium
	Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium
	Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium
	Octyl decyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
	Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium
Category	**Preferred name**	**Synonym**
Iodophors	Nonylphenoxy polyethoxyethanol iodine complex	Nonoxynol iodophor A-P-nonylphenyl-omega-hydroxypoly oxyethylene iodine complex
	Polyethoxy polypropoxy polyethoxy ethanol iodine complex	Iodine polyethoxy polypropoxy polyethoxy ethanol
Chlorine releasing compounds	Calcium hypochlorite	
	Sodium hypochlorite	
Anionic surfactants	Dodecyl benzene sulfonic acid	
	Sodium dodecyl benzene sulfonate	
	Sulfonated oleic acid, sodium salt	

Hydrogen peroxide, peracetic acid, acetic acid solutions	Hydrogen Peroxide	
	Peracetic acid	Peroxyacetic acid
	Acetic acid	

Appendix B

Sanitisers / Cleaners

Nonactive Ingredients*

Preferred name	Synonym
citric acid	
ethoxylated alkyl phenols	
ethyl alcohol	ethanol
hydroiodic acid	
1-hydroxyethylidene-1,1- diphosphonic acid	HEDP
isopropyl alcohol	isopropanol
phosphoric acid	orthophosphoric acid
potassium carbonate	
potassium hydroxide	
propylene glycol	
propylene oxide and ethylene oxide, block copolymer	
sodium carbonate	
sodium hydroxide	
tetrasodium ethylene diaminetetraacetate	tetrasodium EDTA

* Use of these nonactive ingredients in sanitisers/cleaners must be considered to be in accordance with the criteria set forth under Item II, c) above.

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